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# **SUMMARY STATEMENT OF SAFETY and EFFECTIVENESS**

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In accordance with the provisions of the Safe Medical Device Act of 1990, Codonics, Inc. is providing a summary of safety and effectiveness information regarding the Codonics NP-1600M and NP-1600MD Medical Color Printer.

## **General Safety and Effectiveness Concerns:**

The device labeling contains instructions for use, indications for use and cautions as applicable.

All hardware components of the Codonics NP-1600M and NP-1600MD have components that have UL, CUL (CSA equivalent), TUV, CE, and FCC certification.

## **Validation of Effectiveness**

Extensive testing of the device has been performed by technical users, by non-technical users and by potential customers. There is no lossy compression used with this device. Image quality has been verified by radiologists who compared hard copy images printed on the system compared with the original CRT images.

## **Substantial Equivalence**

The Codonics NP-1600M and NP-1600MD Medical Color Printer produces continuous photographic quality hard copies of electronically created or stored images. The primary intended use of this device is to create hard copy prints or transparencies of medical images acquired from computer networks typically used in a medical environment. The intended use and technological characteristics of the system are practically identical to the Kodak XL7720 line of large format continuous tone printers. Any differences between the Codonics, Inc. NP-1600M and NP-1600MD and the equivalent device have no significant influence on safety or effectiveness.

It is our conclusion that there is no hardware device or software component that we know of in the Codonics, Inc., NP-1600M and NP-1600MD whose failure or latent system design flaw would be expected to result in death or injury to a patient